

Attachment A

0517030EP

PTO 2005-1131

Translated from the GERMAN

European Patent Office

EUROPEAN PATENT APPLICATION

0 517 030 A2

IPC: A61F 2/44

Application number: 92108405.9

Date of application: May 19, 2005

Priority: June 4, 1991 DE 4118316

May 8, 1992 DE 4215137

Date the unexamined patent application, on which no grant has taken place on or before the said date, has been made available to the public by printing or a similar process: December 9, 1992 in 'Patentblatt' 92/50

Designated high contracting parties to regional patent conventions: CH DE FR GB IT LI

Applicant: MAN Ceramics GmbH

Inventor: Wolfgang Siebels, Spitzwegstraße 17, D-8360 Deggendorf and Rudolf Ascherl, Türkenstraße 53, D-8000 Munich

[Title in German of the object of the invention:]
Wirbelkörperimplantat

INTRAVERTEBRAL BODY IMPLANT

The invention pertains to an intravertebral (intraspinal) body implant for vertebral (spinal) columns consisting of at least a rigid element.

Intravertebral bodies have different size along a spinal column, and vary from patient to patient. Therefore, when an

intravertebral body is substituted by an implant, it is necessary that the implant is matched to the effective size of the interval between the adjacent intravertebral bodies.

In order for an allowance to be made for this interval, implants were developed (DE 30 23 942 C3), which essentially consist of two parts, which are connected to one another by means of a threaded connection, and whose axial height can be changed by rotation, or which can be matched to the interval between the intravertebral bodies. By means of transverse bolts or other means of anchoring, the two parts are anchored in a way, which is resistant to torsional stress or prevents a rotation. Therewith, by means of a single embodiment an entire range of intervals can indeed be covered, however the adjustment in height takes relatively much time in the case of a fine thread.

An implant of the generic kind, which rectifies this imperfection, is known from the WO 90/00037, which implant is inserted solely between two vertebrae by means of a tool. However, the approximately rectangular implant is assembled out of intricate individual parts.

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is

achieved with the help of the features, cited in claim 1.

Not only is a disk easily inserted into a spinal gap but it can also be manufactured in such a way that it can very easily and dimensionally correct be matched to a certain case of application. For example, in the case of a specific application, it is thus possible that first of all the disk is cut out of a prefabricated solid or hollow strand, sterilized, or separated in sterile state with the help of a sterile grinding tool and sterile water. By using a coarse-grained grinding, respectively cutting tool, a rough surface, promoting the growth process, is imparted to the sectional areas of the implant [spinal] disk, which form the support for the intravertebral bodies.

Basically, the use of a disk of any configuration, be it of round, polygonal, irregular contour, is possible. Also, the inner contour of an annular disk can be created as occasion demands.

The contact surface of a disk, which is being used for the adjacent intravertebral bodies, is designed as structured for the promotion of the growth process, and is selected as being coarse, or running in different directions. Anchoring means in the form of projecting tips or spikes are used for the immediate securing of the prosthesis after the implantation takes place.

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists

of a multiple number of braiding layers (plaiting layers). The braiding layers, are wound up one after another on a correspondingly shaped mandrel (arbor), preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

In accordance with yet another embodiment of the invention, two or more disks are assembled, in order for an intravertebral body implant to be produced. In that case, a stock of an assortment of disks, having different height and diameter, is kept, available at hand. For the purposes of an implantation, the interval between the vertebrae is measured, and correspondingly thick, respectively high, disk of the assortment are combined together in such a way, that they have the desired vertical dimension in their entirety. The selected disks - they consist of parts of analogous shape, only having different height - are stacked one above another, in accordance with the modular principle, and are inserted as ready-made implant between the intravertebral bodies, which - to this end- are slightly pulled apart. Also, in this case, after the insertion of the implant, a regulation or adjustment of the latter inside the patient body is not required.

With the help of a computer, the disks' heights, which are to be combined, are instantaneously determined so that a minimal time input is required between the spinal interval measurement and the reception of the insertable implant. The radial anchoring, and the anchoring, preventing a rotation and resisting the torsional stress, of the assembled disks, can be mastered in a multifarious way.

In accordance with an embodiment of the invention, the disks have aligned boreholes, into which anchoring pins or studs can be inserted. In that embodiment, the disks are radially connected to one another, and also in such a way that they resist the torsional stress [i.e. possess torsional strength], and cannot rotate. Moreover, from a manufacturing engineering standpoint, the manufacturing of the disks is very easy.

Another possibility consists in that the disks are directly produced as having molded anchoring means, such as, e.g., groove and tongue, pin [stud] and boreholes.

Also, the disk packages can be designed as annular disks whereby the hollow space is filled with bone material or bone cement for the purposes of a radial anchoring of the rings. It is advantageous when the inner jacket of the annular disks is irregular, or has geometrical irregularities. Each deviation from the circular cylindrical shape is used for a torsionally resistant anchoring of the stacked disks when the hollow space of the annular disks is filled up with a hardening material. In

order for a reliable support of the implant - which is designed as a disk stack - to be achieved between adjacent intravertebral bodies, end-disks are provided, having a rough frontal side. The roughness can be generated by means of a structured area, projecting tips, undulations, and similar.

In each embodiment, it is possible to glue the disks with one another into a solid unit, e.g., with the help of PMMA* cement, if required, or if functionally feasible. [*Translator's note: PMMA = polymethyl methacrylate].

Preferably, the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all image-producing methods (CT*, MR*) [*Translator's note: CT = charge-transfer (absorption band or electron-transfer band); MR = magnetic resonance)].

Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled

through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.

Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.

The invention is elucidated in greater detail by means of exemplified embodiments, diagrammatically represented in the drawing, wherein

Figs. 1 and 2 show a first exemplified embodiment,

Figs. 3 and 4 show a second exemplified embodiment

Figs 5 thru 8 show another exemplified embodiment, each.

The notion that the surgeon directly assembles the spinal body substitute (replacement set) on the very spot by knowing the actual overall dimensions and without the help of a prosthesis

technician, forms the basis of the invention. To this end, a stock of strands, having different diameter and/or a supply of an assortment of spare implant components, having different diameter and height, is maintained so that for each relevant case either a corresponding thick disk needs to be separated from the relevant strand, or the relevant number of components, having relevant dimensions ought to be taken out, and assembled without threaded [screw] adjustments or other types of handling. In the last case, the selection of the disks according to their height can take place by means of a computer.

The base of an assembled implant consists in the stacking of prefabricated disks whereby these disks can have a round, polygonal or irregular outer contour. Solid disks or also annular disks can be used in their capacity as components. Disk assortment sets, having different diameters, are necessary whereby each assortment of a diameter is outfitted with disks, having different diameter. If one is absolutely certain about the diameter of the disk to be used, the corresponding heights are yet to be selected within the framework of the corresponding disk batch [assortment set] so that after the selected disks are assembled, the required implant height is thus produced.

For example, in order for the assortment with respect to the disk height to be maintained as small as possible, few high dimensions can be provided, which are correspondingly supplemented with lower disks, e.g., having a thickness of

several millimeters.

Fig. 1 shows an exemplified embodiment, in which a ready-made implant 10 is assembled out of three thicker disks 11, a thin disk 12, and two end-disks 13 and 14.

As diagrammatically represented in Fig. 2, the disks, 11 thru 14, consist of round annular disks, having an inner borehole 15, and four boreholes 16, respectively, which are equitably distributed over the annular disk. Anchoring pins [studs] 17 are introduced into these boreholes 16. In accordance with the embodiment, depicted in Fig. 1, the pins 17 are connected with one of their respective ends 18 to a disk 11, 13 while they protrude with the other end 19 into the borehole of the subsequent disk 11. In this embodiment, an end-disk 14 is designed without pin [stud]. In an analogous way, the thin disks 12 have solely boreholes 16.

Self-evidently, it is also possible to produce the pins as structural components separated from the disks 11 thru 14 so that the pins are introduced into the boreholes 16 only when the assembly of an implant 10 takes place.

Instead of pins, groove-and-tongue systems can also be provided as anchoring means in each possible configuration.

Fig. 3 shows an exemplified embodiment, in which the disks 21 are provided with an annular [ring] spring 22 on one of the frontal sides whereas, on the other frontal side, they are provided with an annular groove 23, aligned with the annular

spring 22. In order for an anchoring to be also achieved in the torsional direction, spring segments 24 can be provided instead of the annular [ring] springs 22, as indicated by the dotted line in Fig. 4, which spring segments engage into corresponding grooved segments of the next disk.

In the diagrammatically represented exemplified embodiments, there were shown round disks, having a circularly symmetric distribution of the anchoring elements. It is self-evident that any asymmetric arrangement of the anchoring elements as well as of any outer contour of the disks is possible as long as the latter are in agreement with the contour of the intravertebral bodies.

From the standpoint of manufacturing engineering, annular disks or solid disks can easily be manufactured of any biologically compatible material because they are not bound to a particular shaping. The shape can even partially be matched to the manufacturing method. Manufacturing methods, which are adequate for the series-manufacturing are winding or pulling of bonded-fiber tubes, out of which the disks are sawn off, cut off, or separated, either as individual element or as elements for the disk packings [packages], described above. In the winding method, fibers or fibrous mats are used in accordance with known methods. In the braiding method, as depicted in Fig. 5, a correspondingly shaped bar-shaped mandrel 30, e.g., having a rectangular cross-section, is passed through a thread eyelet [guide] 31, and, in

doing so, it is surrounded with bundles of longitudinally directed, unidirectional (UD) fibers 32, impregnated with matrix, as well as with outer braiding fibers 32. After the solidification of the matrix, annular disks 35 are separated out of the bonded-fiber tube thus produced, whereby the mandrel is removed prior to or after the separation of the annular disks. The strand, which is designed as bonded-fiber tube, is used for the manufacturing of individual disks as well as for the manufacturing of a disk package, as depicted in Fig. 1.

When needed, individual disks 35 are separated as wedge-shaped ones (Fig. 6, $(h_1 > h_2)$). In the neutral area 37.. there can be provided openings 38, which are used to engage the implantation tools and fixation means, such as staples [cramp irons; clamps; or clips] 39.

The hollow space 36 can be filled up with extraneous bone material, or with patient's own bone material, or with bone cement, which can also be introduced through the opening 38. When the disks are assembled, the bone cement is also used for the anchoring of the disks in the radial direction, and - due to the non-circular symmetric inner cross-section 36 - in the torsional direction as well. Instead of the rectangular inner cross-section, any other configuration - save the circular shape - can be selected, in order for a free rotational motion between the disks to be precluded.

Fig. 7 shows a shape, having a cylindrical inner jacket 40, which is outfitted with an elevation 42 for torsional anchoring.

If need arises, the disks or annular disks are provided with a starter foil 43- as shown in Fig 7 - surrounding adhesive cartridges 44. When two disks 45 for the formation of the implant are placed one above another, and axially compressed, the adhesive cartridges 44 burst open, so that the adhesive is distributed between the disks 45, and connects the disks with one another. The adhesive connection can be used as single connection or supplementarily to the aforementioned anchoring means.

In the embodiment in accordance with Fig. 7, there are shown additional boreholes 46, which are radially guided through the annular disk 45. They are used for the introduction of the bone cement or bone material into the hollow space 47.

On their free frontal end, used as the support for the spinal bones, the end-disks 13, 14 of an implant 10 have a surface 20, which is rough, structured, or provided with discrete elevations. In interaction with the adjacent intravertebral bodies 50, 51, which are pressing against the implant 10, the said elevations should guarantee the anchoring inside the spinal column, and be used as growth help. As described above, bone cement or material 53 can be pressed - if need arises - through a non-diagrammatically represented radial borehole into the inner borehole 15 up to the adjacent intravertebral body 50, 51. In the case of a single-disk implant, both sides are correspondingly

designed. A rough surface can be directly formed within the framework of the separation process from strand by using a coarse-grained cutting tool.

The implantation of an intervertebral disk substitute and/or an intravertebral fibrocartilage [intravertebral ligament; intervertebral cartilage] of this kind is not subject to any system-specific problems. If the surgical step has gone so far that the interval between the adjacent vertebral bodies can be adjusted, the assembly of the disk-heights for the implant is calculated in the computer with the help of this value, selected, and assembled, or with the help of a precisely adjustable tool, the disk is separated from the strand. The adjacent vertebral bodies are somewhat pulled apart, and the implant, respectively the disk, assembled within the framework of the modular method, is inserted. As far as the implant is concerned, no additional manipulation procedures or handling are necessary save for the placement of the implant. Besides the implant height, the diameter of the implant also varies. Hence, the disk and/or strand assortment is also to be supplied according to cross-sectional areas.

Finally, in Fig. 8, there is shown a hollow strand 50, having an irregular configuration, which hollow strand is formed out of 1 to 20 braidings 51. A mandrel, which is not diagrammatically represented, is often pulled through the annular thread eyelet of a braiding machine, and, in doing so, lined with

many braidings and matrix material, respectively. With the help of separating disks, the disks 53 for an implant or implant element, are cut out at separating lines 52.

Patent Claims

1. Implant for spinal columns, consisting of at least a rigid element, characterized in that the implant consists of at least a disk (11 thru 14, 21, 35, 45, 53), which can be directly inserted between two adjacent vertebral [intravertebral] bodies, and according to the spinal position has parallel contact surfaces [support surfaces] or contact surfaces, which are at an angle with respect to one another.

2. Implant as claimed in claim 1, characterized in that the disk is designed as annular disk (35, 45, 53), having regular or irregular circumference, and that the inner circumference of the disk has a polygonal or irregular cross-section.

3. Implant as claimed in claim 1 or 2, characterized in that the contact surfaces of the disks (14, 25, 53) have roughness, pore undulations, or other unevennesses.

4. Implant as claimed in claim 1, characterized in that the contact surfaces of the disks (14, 35, 53) have protruding tips or spikes (20).

5. Implant as claimed in one of the preceding claims, characterized in that the disk (45) has channels (46) into which bone cement or bone material can be introduced.

6. Implant as claimed in one of the preceding claims, characterized in that the disks (11 thru 14, 21, 35, 45, 53) consist of fiber-reinforced plastic, and are made within the framework of the winding method or of wound up [batched up] fiber mats [fiber webs].

7. Implant as claimed in one of the preceding claims, characterized in that the disk (53) is cut out of a strand (32, 33, resp. 50).

8. Implant as claimed in claim 7, characterized in that the strand [hank; rope] (32, 33 or 50) consists of unidirectional fibers (32 and/or braiding layers (31, 51).

Translated by John M Koytcheff, M.Sc. (Engrg.);
Postgraduate WHO Fellow (Env. Engrg.); USNWC Alumnus

The USPTO Translator (GERMAN & Germanic languages)
US DEPARTMENT OF COMMERCE/USPTO/STIC/Translations Branch
December 7, 2004

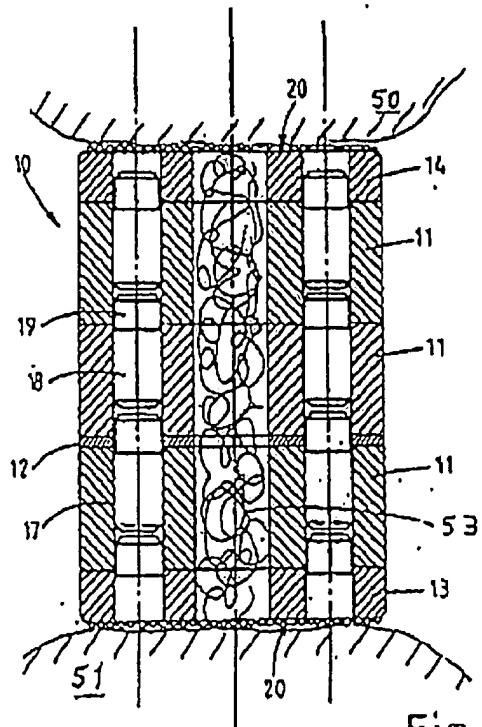


Fig. 1

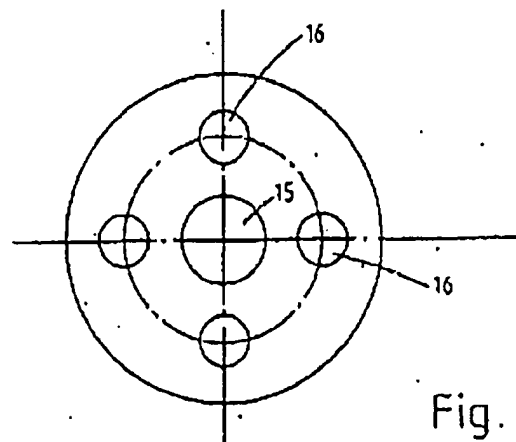


Fig. 2

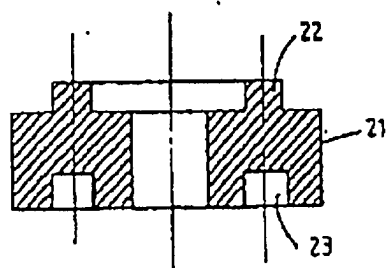


Fig.3

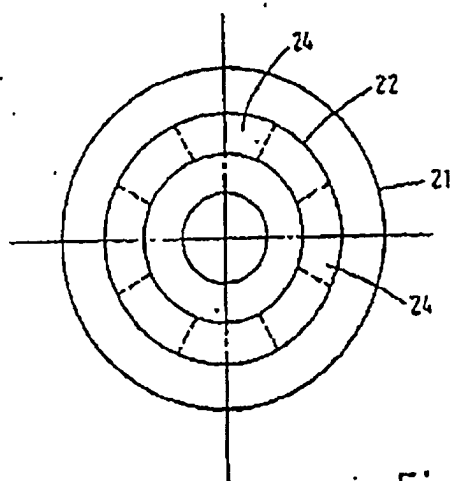


Fig.4

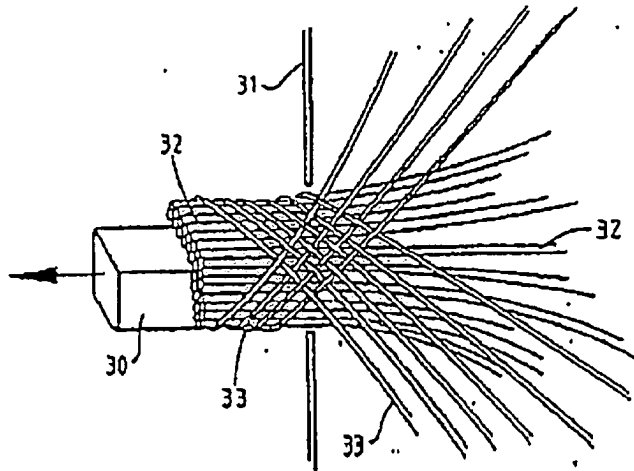


Fig. 5

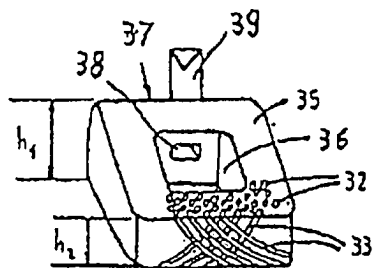


Fig. 6

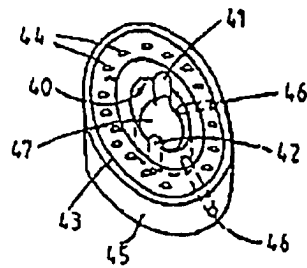


Fig. 7

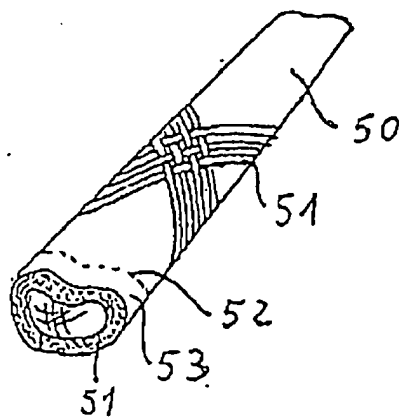


Fig. 8